Biologische tumorkenmerken voorspellend voor de respons op chemoradiotherapie bij slokdarmkanker

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23044

Source
NTR

Brief title
MORE

Health condition

non-metastastatic esophageal cancer
niet uitgezaaid slokdarmkanker

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden. investigator initiated
Source(s) of monetary or material Support: Stichting De Friesland

Intervention

Outcome measures

Primary outcome

The main study parameters are differences in kinetic profile and/or genetic profile between patients with and without a pathologic complete response after chemo radiation.

Secondary outcome

The association of the created predictive profile and relapse/survival outcome parameters

Study description

Background summary

Single-centre study

Study objective

The objective of the MORE studies is to select and validate a biomarker profile predictive for the response to weekly paclitaxel and carboplatin chemotherapy concomitant with radiotherapy in patients with esophageal cancer.
In the MORE-1 pilot study candidate biomarkers are selected using a multimodal approach combining genomics (next generation sequencing) and proteonomics/kinomics (kinase activity profiling). The objective of the MORE-2 study is to validate the classifier that is developed in the MORE-1 study in patients treated with definitive chemo radiation (without surgery).

Study design

response after surgery en 2 year follow-up for diseasefree survival and overall survival

Intervention

Staging and treatment will be performed according to local and Dutch treatment guidelines. During the regular endoscopic ultrasonography (EUS) staging procedure 4 extra biopsies for biomarker testing will be taken from the primary esophageal tumor. One extra blood sample for genetic analyses purposes will be collected combined with a regular chemotherapy associated blood collection.

Contacts

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Eligibility criteria

Inclusion criteria

All patients referred to MCL with pathologically proven carcinoma of the esophagus and without distant metastases will be asked to participate

Exclusion criteria

none

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015

Enrollment:	85
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-07-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42549
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4821
NTR-old	NTR5323
CCMO	NL53633.099.15
OMON	NL-OMON42549

Study results